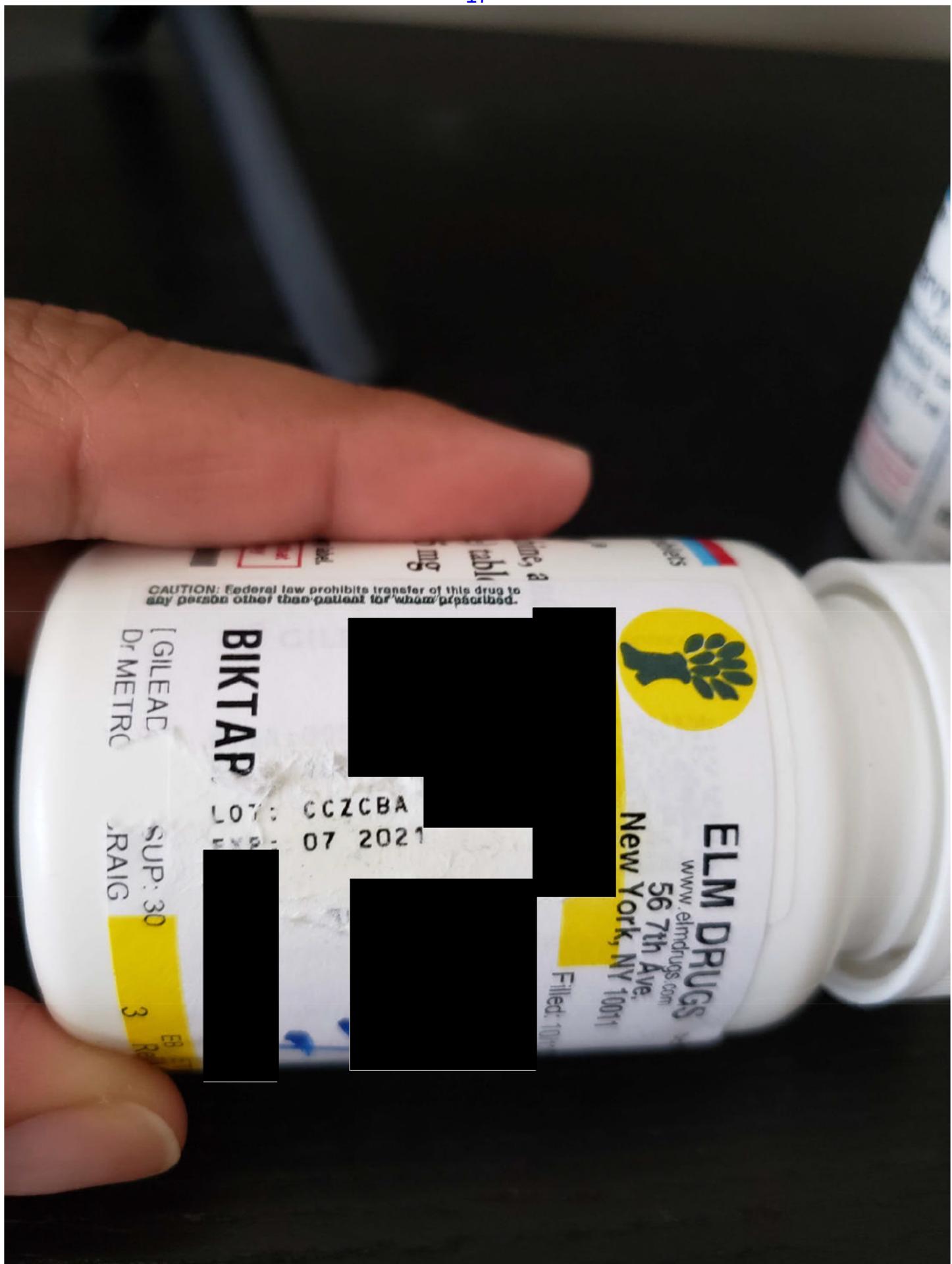
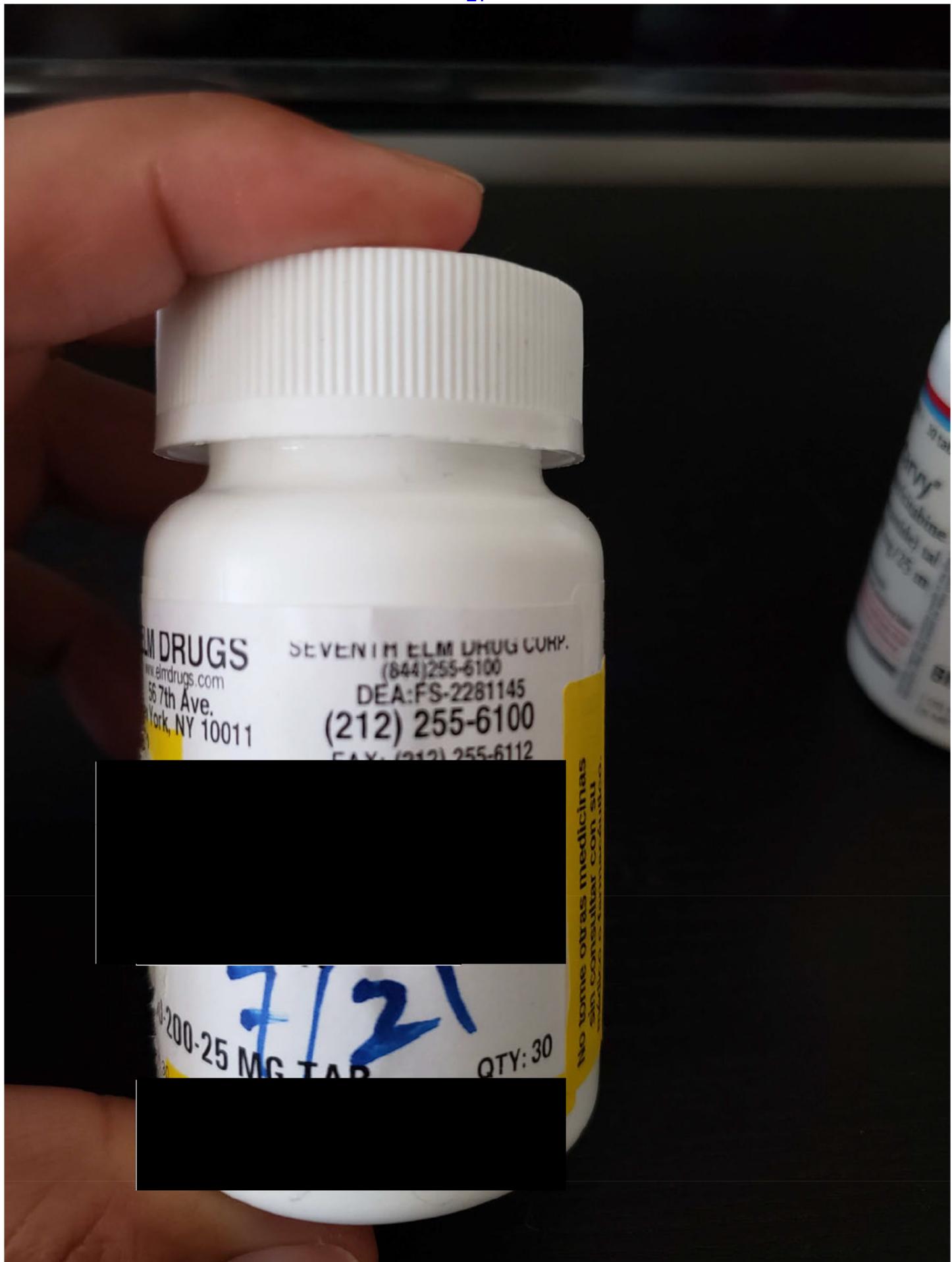




GX 631.0001



GX 631.0002



GX 631.0003



GX 631.0004



GX 631.0005



GX 631.0006



GX 631.0007

**From:** [REDACTED]  
**To:** [Zayas, Cesar D \(OIG/OI\)](#)  
**Subject:** Fwd: [EXTERNAL] Re: Gilead Sciences BIKTARVY(R) Complaint (PR-213442)  
**Date:** Tuesday, April 30, 2024 11:42:03 AM

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**CAUTION:** External email. Do not click links or open attachments unless you recognize the sender and know the content is safe.

----- Forwarded message -----

From: **Quality Complaints** <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)>  
Date: Thu, Mar 18, 2021 at 6:06 PM  
Subject: RE: [EXTERNAL] Re: Gilead Sciences BIKTARVY(R) Complaint (PR-213442)  
To: [REDACTED] <[\[REDACTED\]@gmail.com](mailto:[REDACTED]@gmail.com)>  
CC: Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)>

Hello [REDACTED]

I received an update from TheraCom, who confirmed that they have received the prescription for your replacement bottle. Please expect a call from TheraCom as they will want to confirm your information and schedule delivery of the replacement bottle.

Kind regards,

**Clifford Won**

QA Specialist I | Quality Systems & Operations  
Gilead Sciences, Inc. | [333 Lakeside Drive, Foster City, CA 94404](#)  
Phone: 800-445-3235 option #2 | Email: [QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)

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**From:** Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)>  
**Sent:** Thursday, March 18, 2021 2:38 PM  
**To:** [REDACTED] <[\[REDACTED\]@gmail.com](mailto:[REDACTED]@gmail.com)>  
**Cc:** Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)>  
**Subject:** RE: [EXTERNAL] Re: Gilead Sciences BIKTARVY(R) Complaint (PR-213442)

Hello [REDACTED]

We have concluded our investigation. Please see the attached closure letter for your record.

I spoke with your doctor's office yesterday and they said that a prescription for your replacement bottle was electronically sent to our TheraCom Specialty Pharmacy. I am working with TheraCom to determine the delay in getting your replacement bottle shipped to you. I will keep you posted.

Please let me know if you have any questions.

Kind regards,

**Clifford Won**

QA Specialist I | Quality Systems & Operations

Gilead Sciences, Inc. | [333 Lakeside Drive, Foster City, CA 94404](https://www.gilead.com)

Phone: 800-445-3235 option #2 | Email: [QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)

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**From:** Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)>  
**Sent:** Friday, March 12, 2021 8:49 AM  
**To:** [REDACTED] [REDACTED] @gmail.com>  
**Cc:** Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)>  
**Subject:** RE: [EXTERNAL] Re: Gilead Sciences BIKTARVY(R) Complaint (PR-213442)

Hello [REDACTED],

I hope you are doing well. Thank you for returning your complaint bottle of BIKTARVY to Gilead QA. I would like to provide an update on your replacement bottle. I spoke with Patty at Dr. Metroka's office last week and she said she would have the doctor send a prescription to our TheraCom Specialty Pharmacy. I received an update from TheraCom that they have not

received the prescription for the replacement bottle. I left a voicemail message for the doctor's office this morning, and will continue to follow up with them for the prescription.

Please let me know if you have any questions.

Kind regards,

**Clifford Won**

QA Specialist I | Quality Systems & Operations

Gilead Sciences, Inc. | [333 Lakeside Drive, Foster City, CA 94404](https://www.gilead.com)

Phone: 800-445-3235 option #2 | Email: [QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)

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**From:** Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)>  
**Sent:** Wednesday, February 24, 2021 8:17 AM  
**To:** [REDACTED] [REDACTED]@gmail.com>  
**Cc:** Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)>  
**Subject:** RE: [EXTERNAL] Re: Gilead Sciences BIKTARVY(R) Complaint (PR-213442)

Hello [REDACTED]

Can you please let me know if you brought the complaint sample to a FedEx drop-off location? Or would you like me to schedule a FedEx pickup at your address?

Kind regards,

**Clifford Won**

QA Specialist I | Quality Systems & Operations

Gilead Sciences, Inc. | [333 Lakeside Drive, Foster City, CA 94404](https://www.gilead.com)

Phone: 800-445-3235 option #2 | Email: [QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)

**From:** Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)>  
**Sent:** Tuesday, February 23, 2021 10:37 AM  
**To:** [REDACTED] @gmail.com>  
**Cc:** Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)>  
**Subject:** RE: [EXTERNAL] Re: Gilead Sciences BIKTARVY(R) Complaint (PR-213442)

Hi [REDACTED],

Great, thank you! Please use the attached prepaid FedEx label.

Just to update you on the product replacement, our TheraCom Specialty Pharmacy is working on getting a prescription from your prescriber's office.

Please let me know if you have any questions.

Kind regards,

**Clifford Won**

QA Specialist I | Quality Systems & Operations  
Gilead Sciences, Inc. | [333 Lakeside Drive, Foster City, CA 94404](https://www.gilead.com/careers/locations/333-lakeside-drive-foster-city-ca-94404)  
Phone: 800-445-3235 option #2 | Email: [QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)

**From:** [REDACTED] @gmail.com>  
**Sent:** Tuesday, February 23, 2021 10:27 AM  
**To:** Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)>  
**Subject:** Re: [EXTERNAL] Re: Gilead Sciences BIKTARVY(R) Complaint (PR-213442)

Yes I will just email me the label

On Tue, Feb 23, 2021, 1:25 PM Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)> wrote:

Hello [REDACTED]

It appears that the FedEx return label that I sent out on February 16<sup>th</sup> has not yet been delivered to your address. Since this is an unexpected delay, would you be able to ship back your complaint sample if I emailed a prepaid FedEx label? (Would you be able to print out the label and package the sample?)

Kind regards,

**Clifford Won**

QA Specialist I | Quality Systems & Operations

Gilead Sciences, Inc. | [333 Lakeside Drive, Foster City, CA 94404](https://www.gilead.com)

Phone: 800-445-3235 option #2 | Email: [QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)

**From:** [REDACTED] [REDACTED] [@gmail.com>  
\*\*Sent:\*\* Friday, February 19, 2021 8:59 AM  
\*\*To:\*\* Quality Complaints <\[QualityComplaints@gilead.com\]\(mailto:QualityComplaints@gilead.com\)>  
\*\*Subject:\*\* Re: \[EXTERNAL\] Re: Gilead Sciences BIKTARVY\(R\) Complaint \(PR-213442\)](mailto:@gmail.com)

Hello

Yes I'm still taking Biktarvy and I have a bottle right now in use.

And also I just want to let you know that the bottle that I have to send you back has 29 pills, but since I was talking with my lawyer about this situation I will keep 2 of the pills as an evidence for my protection because up to date I still feeling the effects of that medicine I need to keep that evidence on my hands together with all the documentation, doctor report and pictures I have taken so far comparing both bottles, with that being said I will be sending you back the bottle with all the elements that came with it but with 27 pills inside and will keep 2 for my evidence.

Thanks

[REDACTED]

On Fri, Feb 19, 2021, 11:50 AM Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)> wrote:

Hello [REDACTED]

I hope this email finds you safe and warm. Apologies that I did not acknowledge your email sooner. I wanted to let you know that I am continually tracking the FedEx return label that was sent out on Tuesday, February 16<sup>th</sup>. Due to the inclement weather that your part of the country is experiencing, there is a delay in the return label being delivered to your address.

As soon as it is delivered, can you please ensure that all contents of your BIKTARVY bottle is shipped back to us? This includes the induction seal on the bottle, polyester fiber coil (“cotton ball”), and foreign tablets. We would like to perform lab analysis for our investigation.

Can you please confirm that you are still on treatment with BIKTARVY? Do you have another bottle that you are taking your medication from?

Please let me know if you have any questions.

Kind regards,

**Clifford Won**

QA Specialist I | Quality Systems & Operations

Gilead Sciences, Inc. | <333 Lakeside Drive, Foster City, CA 94404>

Phone: 800-445-3235 option #2 | Email: [QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)

**From:** [REDACTED] @gmail.com>

**Sent:** Tuesday, February 16, 2021 4:52 PM

**To:** Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)>

**Subject:** [EXTERNAL] Re: Gilead Sciences BIKTARVY(R) Complaint (PR-213442)

More pictures attached (3)

On Tue, Feb 16, 2021, 5:14 PM Quality Complaints <[QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)> wrote:

Hello [REDACTED]

Thank you for speaking with me regarding the foreign tablets found your BIKTARVY bottle. I have assigned **PR-213442** for our investigation. Please see the attached acknowledgement letter for your record.

As discussed over the phone, can you please provide answers to the following questions?

- Can you please also provide the GTIN and SN on the bottle? This information can be found above the Lot # and Expiration Date.
- Are there any imprints on the base/underneath the bottle?
- Would you be able to provide photographs of the complaint bottle and all of its content to Gilead? We would like the photographs to show all aspects of the bottle (top of the cap/lid, base/underneath the bottle, inside the cap/lid, inside the bottle), foreign tablets, polyester fiber coil ("cotton"), and/or desiccant. Please send the photographs via email ([QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)) or text message (650-504-7385). Please use the Complaint Sample Photo Template below as reference.
- Would you be able to provide the exact date that the complaint bottle was delivered to you?

Complaint Sample Photo Template

Please do not hesitate to contact me should you have any questions. I can be reached at 800-445-3235 option #2 for Product Complaints or email at [QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com).

Kind regards,

**Clifford Won**

QA Specialist I | Quality Systems & Operations

Gilead Sciences, Inc. | [333 Lakeside Drive, Foster City, CA 94404](https://www.gilead.com/locations/333-lakeside-drive-foster-city-ca-94404)

Phone: 800-445-3235 option #2 | Email: [QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)

SCS-0000125848

From: [REDACTED]  
To: [Zayas, Cesar D \(OIG/OI\)](#)  
Subject: Fwd: Gilead Sciences BIKTARVY(R) Complaint (PR-213442)  
Date: Tuesday, April 30, 2024 11:41:39 AM

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**CAUTION:** External email. Do not click links or open attachments unless you recognize the sender and know the content is safe.

----- Forwarded message -----

From: [REDACTED] [\[REDACTED\]@gmail.com](#)>  
Date: Tue, Feb 16, 2021 at 7:52 PM  
Subject: Re: Gilead Sciences BIKTARVY® Complaint (PR-213442)  
To: Quality Complaints <[QualityComplaints@gilead.com](#)>

More pictures attached (3)

On Tue, Feb 16, 2021, 5:14 PM Quality Complaints <[QualityComplaints@gilead.com](#)> wrote:

Hello [REDACTED]

Thank you for speaking with me regarding the foreign tablets found your BIKTARVY bottle. I have assigned **PR-213442** for our investigation. Please see the attached acknowledgement letter for your record.

As discussed over the phone, can you please provide answers to the following questions?

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- Are there any imprints on the base/underneath the bottle?
- Would you be able to provide photographs of the complaint bottle and all of its content to Gilead? We would like the photographs to show all aspects of the bottle (top of the cap/lid, base/underneath the bottle, inside the cap/lid, inside the bottle), foreign tablets, polyester fiber coil ("cotton"), and/or desiccant. Please send the photographs via email ([QualityComplaints@gilead.com](#)) or text message (650-504-7385). Please use the Complaint Sample Photo Template below as reference.
- Would you be able to provide the exact date that the complaint bottle was delivered to you?

Complaint Sample Photo Template



Please do not hesitate to contact me should you have any questions. I can be reached at 800-445-3235 option #2 for Product Complaints or email at [QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com).

Kind regards,

**Clifford Won**

QA Specialist I | Quality Systems & Operations

Gilead Sciences, Inc. | 333 Lakeside Drive, Foster City, CA 94404

Phone: 800-445-3235 option #2 | Email: [QualityComplaints@gilead.com](mailto:QualityComplaints@gilead.com)